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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

D1068 B

January 3, 1997

19900 MacArthur Blvd., Ste 300
Irvine, California 92715-2445
Telephone (714) 798-7800

Ref: WL-9-7

WARNING LETTER

Hand Delivered

Daniel Bricker, D.C.
Biolife Bioproducts, Ltd
1341 East Valley Parkway
Suite 210
Escondido, CA 92027

Dear Dr. Bricker:

As a result of the significant number of reported injuries to consumers associated with "CHERRY FX BOMBS", "LEMON FX DROPS", and "ORANGE FX RUSH" which are distributed by you, FDA has investigated these products.

Our evaluation of complaints of serious injuries, including reports by those who used the products in accordance with label directions, associated with the consumption of these products shows that they present a significant or unreasonable risk of illness or injury under conditions of use recommended or suggested in the products' labeling. Therefore, these products are adulterated under section 402(f)(1)(A) of the Federal Food, Drug, and Cosmetic Act (the act). This finding does not preclude the possibility that the products also violate other sections of the act.

This notice is being sent to you in accordance with section 402(f)(2) of the act. Within ten (10) working days of receipt of this letter you may present your views in this matter. You may respond in person, by telephone, or in writing. Your response should be directed to:

Thomas L. Sawyer
Leadership Team - Compliance
Food and Drug Administration
19900 MacArthur Blvd., Suite 300
Irvine, California 92612-2445
Telephone: (714) 798-7755

Sincerely yours,

Elaine C. Messa
Elaine C. Messa
District Director